

510(K) SUMMARY

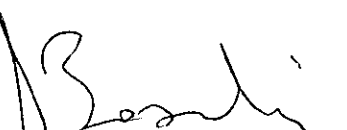
K102036

510(k) owner and submitter	LAMBDA S.p.A. Via Dell'Impresa 1 36040 Brendola (Vicenza) Italy +39 0444 349 165 +39 0444 349 954	SEP 28 2010
Contact person	Mr Boschi Alessandro +39 0444 349 165 boschi@lambdascientifica.com	
The common name of the device	Diode laser	
Trade name / Proprietary names	Doctor Diode Laser Family	
Classification name	Laser surgical instrument for use in general and plastic surgery and dermatology	
Product code	Gex	
CFR Number	21 CFR §878.4810	
Predicate Devices	Doctor Diode Laser Family: <ul style="list-style-type: none"> - Velure Family of Diode Laser (K063396) - Quanta System Polysurge Diode Laser Family (K083613) - Doctor Smile A-810, B980 Lasers (K091562) - Arc Laser GmbH Fox Q-810, Q-980, Q-1064 (K073322) - Biolase Ezlase® (K082938) - Styla Microlaser™ (K081214) - Odissey navigator (K062258) - Sirona Sirolaser (K053161) - Kavo Gentleray 980 (K072262) - Ceralas 980 (K072779) - Claros Nano Dental Laser System (K081652) 	
Product description	Doctor Diode Laser Family are the same standard diode medical lasers respectively with 810, 940, 980, 1064 nm wavelength.	
Intended Use	Doctor Diode Laser Family including Doctor Smile, Doctor Surgery and Helios are available at 810 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w; at 940 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w; at 980 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w and at 1064 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w (and their delivery accessories used to deliver optical energy) are indicated for use !	

	in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.
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Performance standards	The Doctor Diode Laser Family comply with the following standards: IEC 60601-1:1998+A1:1991+A2:1995 IEC 60601-2-22:1995 IEC 60825-1:1993+A1:1997+A2:2001 21 CFR 1040.10 and 1040.11
Device technological characteristics and Comparison to Predicate device(s)	The Doctor Diode Laser Family are portable instruments which transmit laser energy via a contact fiber optic delivery system and each unit is compromised of the following main components: -a laser system console (including display panel, software and control); -a fiber optic delivery system; -one or more handpieces -protective eye ware -optical tips Doctor Diode Laser Family have the same intended use and the same or substantially equivalent technical specifications and mechanism of action as compared with the named predicated devices.
Conclusion:	The Doctor Diode Laser Family have identical or similar indications for use, principles of operation, overall technical and functional capabilities. Therefore is substantially equivalent to the predicate devices. They have similar intended uses and comply with the same safety and performance standards.

Review:


 Boschi Alessandro



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LAMBDA S.p.A.
% Mr. Boschi Alessandro
Via Dell'Impresa n. 1
36040 Brendola (Vicenza)
Italy

SEP 28 2010

Re: K102036

Trade/Device Name: Doctor Surgery Diode Lasers Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 23, 2010
Received: September 23, 2010

Dear Mr. Alessandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

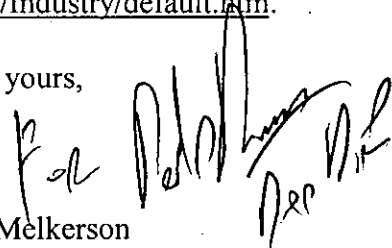
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102036

ATTACHMENT A COPY

Section 4

Indications for Use

510(k) Number (if known): **K102036**

SEP 28 2010

Device name: Doctor Surgery Diode Lasers Family

Indications for use:

Doctor Diode Laser Family including Doctor Smile, Doctor Surgery and Helios are available at 810 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w; at 940 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w; at 980 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w and at 1064 wavelength with variable power of 500mw, 2w, 2,5w, 5w, 7w, 8w, 10w and 15w (and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.

Doctor Diode Laser Family at 810nm's wavelength:

Dental application:

- Excisional and incisional biopsies, Exposure of unerupted teeth, Fibroma removal, Frenectomy, Frenotomy, Gingival troughing for crown impressions, Gingivectomy, Gingivoplasty, Gingival incision and excision Haemostasis and coagulation, Implant recovery, Incision and drainage of abscess Leukoplakia, Operculectomy, Oral papillectomies, Pulpotomy, Pulpotomy as an adjunct to root canal therapy, Reduction of gingival hypertrophy, Soft tissue crown lengthening, Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa, Vestibuloplasty. Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket. Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.). Light activation of whitening/bleaching material.

Doctor Diode Laser Family at 810nm and 980nm's wavelength

Urology:

- Lesions of external genitalia
- Circumcision
- Condyloma
- Bladder tumors
- Bladder neck incisions
- Vaporizations of the prostate

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General Surgery:

- Rectal and anal hemorrhoidectomy
- Mastectomy
- Dermabrasion
- Appendectomy (open and laparoscopic)
- Bowel resection (open and laparoscopic)
- Colectomy
- Liver resection
- Resection of organs
- Thyroidectomy
- Adhesiolysis
- Hepatobiliary tumors
- Thoracotomy
- Cholecystectomy (open and laparoscopic)
- Condyloma
- Breast biopsy

Neurosurgery:

- Percutaneous Disc Decompression (PLDD)
- Discectomy
- Hemostasis in conjunction with meningiomas

Gynecology:

- Cervical conization
- Myomectomy
- Endometrial ablation
- Ovarian cystectomy
- Appendectomy

Ophthalmology:

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor excision
- Blepharoplasty

Orthopedics:

- Dissect and coagulate

Gastroenterology:

- Hemostasis of colonoscopy
- Hemostasis of esophageal varices
- Excision of polyps

Arthroscopy:

- Chondromalacia
- Synovectomy
- Meniscectomy

Thoracic Surgery:

- Thoracotomy


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- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

Pulmonology:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary obstruction

Otolaryngology ENT:

- Removal of benign lesions from the ear, nose and throat
- Excision of carcinoma of the larynx
- Incision and excision of carcinoma in situ
- Neck dissection
- Laryngeal papillomectomy
- Removal of vocal cord/fold nodules, polyps and cyst

Pulmonary Surgery:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary or stricture

Cardiac Surgery:

- Coagulation and hemostasis of cardiac tissue

Dermatology/Aesthetics:

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinullectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigments lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminata, warts, small non malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridement.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

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Plastic Surgery:

- Cut, coagulation & vaporization
- Resurfacing non
- Blepharoplasty

510(k) Number K 102036

Vascular Surgery:

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

Doctor Diode Laser Family at 940nm wavelength:

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Radiology, Dentistry.

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, and for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85 cc.

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including marginal and inter-dental gingival and epithelial lining of free gingival and the following specific indications: Excisional and incisional biopsies Exposure of unerupted teeth; Fibroma removal; Frenectomy; Frenotomy; Gingival troughing for crown impressions; Gingivectomy; Gingivoplasty; Gingival incision and excision; Haemostasis and coagulation; Implant recovery; incision and drainage of abscess; Leukoplakia; Operculectomy; Oral papillectomies; Pulpotomy as an adjunct to root canal therapy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa; Vestibuloplasty;

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for Laser Periodontal procedures, including: Laser soft tissue curettage; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed, and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).

Doctor Diode Laser Family at 980nm wavelength:

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in the ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein.

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology):

Hemostasis, incision, excision ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include:

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in situ
- Ablation and vaporization of hyperkeratosis

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Apparecchiature Laser / Laser Equipment - Sensori e Sistemi di monitoraggio / Monitoring Systems and Sensors

- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection
- Tonsillectomy
- Thyroidectomy
- Vocal cord polypectomy
- Hemiglossectomy
- Tracheal stenosis
- Oral cavity lesions

Arthroscopy:

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:

- Meniscectomy
- Synovectomy
- Chondromalacia

Gastroenterology:

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

General Surgery, Dermatology, Plastic Surgery and Podiatry:

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion. Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and hemostasis of capillary hemangioma
- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy

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510(k) Number K102036

- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Photocoagulation of teleangiectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux
- Treatment of reticular veins and branch varicosities

Urology:

Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues. Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyoma
- Lesions of external genitalia
- Vaporization of the prostate to treat benign prostatic hyperplasia (BPH)

Gynecology:

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

Neurosurgery:

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue.

Examples include: hemostasis in conjunction with meningiomas.

Cardiac Surgery:

Hemostasis and coagulation of soft tissue, including cardiac tissue.

Pulmonary Surgery:

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system.

Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

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 and Restorative Devices

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Dental Applications:

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and

sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux:

Coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

Doctor Diode Laser Family at 1064nm wavelength:

Dermatology/Plastic Surgery:

Photocoagulation:

- Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful)


Discectomy:

Percutaneous Lumbar Discectomy

Gastrointestinal:

Tissue Ablation:

- Benign and malignant Neoplasm
- Polyps
- Colitis
- Ulcers
- Aniodysplasia
- Hemorrhoids


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Hemostasis:

- Varices
- Esophangitis
- Esophageal Ulcer

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Pulmonary Surgery:

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system.

Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

Dental Applications:

The Doctor Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux:

Coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

Doctor Diode Laser Family at 1064nm wavelength:

Dermatology/Plastic Surgery:

Photocoagulation:

- Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful)

Discectomy:

Percutaneous Lumbar Discectomy

Gastrointestinal:

Tissue Ablation:

- Benign and malignant Neoplasm
- Polyps
- Colitis
- Ulcers
- Aniodysplasia
- Hemorrhoids

Hemostasis:

- Varices
- Esophangitis
- Esophageal Ulcer

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Prostatectomy:

Soft Tissue Coagulation:

- Benign Prostatic Hyperplasia (BPH Prostatectomy)

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Pulmonary Surgery:

Palliative Treatment:

- Benign and Malignant Pulmonary Airway Obstructions

Dental procedures

Prescription use XX

and/or

Over-the-counter use _____

(21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

Review:

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Boschi Alessandro